

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 3

**REMARKS**

In accordance with 35 U.S.C. §120, Applicant has amended the Specification to claim priority of the parent patent application U.S. Serial No. 09/928,178, filed August 9, 2001, which claims priority to U.S. Provisional Application, U.S. Serial No. 60/224,112, filed August 9, 2000.

Applicant also canceled claims 1, 4-22, 25-64, 66 and 68-84 to reduce filing fees without prejudice to the Applicants' rights to pursue the subject matters in a future application.

Accordingly, there are no issues of new matters and Applicant respectfully requests the entry of this Amendment. Upon entry, claims 2-3, 23-24, 65 and 67 will be pending and under examination.

This application is a continuation application of U.S. Serial No. 09/928,178. On May 06, 2003, a Final Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the May 06, 2003 Final Office Action was originally due August 06, 2003. On November 6, 2003, Applicant submitted a Notice of Appeal and a petition for three-month extension. Applicant enclosed a check for FOUR HUNDRED AND SEVENTY-FIVE DOLLARS (\$475.00) to cover the fee for the petition for three-month extension of time and a check for ONE HUNDRED AND SIXTY-FIVE DOLLARS (\$165.00) to cover the fee for the filing of the Notice of Appeal with the November 6, 2003 Notice of Appeal and the petition for three-month extension of time, and authorized the Commissioner to charge any additional fee(s) to Deposit Account No. 50-1891.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 4

A Response to the May 06, 2003 Final Office Action was due November 06, 2003. Accordingly, the November 6, 2003 Notice of Appeal was timely filed.

A response to the November 6, 2003 Notice of Appeal was originally due January 06, 2004. On March 8, 2004, Applicant petitioned for a two-month extension of time and authorized the Commissioner to charge the corresponding fee of TWO HUNDRED AND TEN DOLLARS (\$210.00) to Deposit Account No. 50-1891. Accordingly, a Response to the November 6, 2003 Notice of Appeal was due March 6, 2004, which is a Saturday. Since a Response is due the next business day when the deadline falls on a Saturday, Sunday or a federal holiday, i.e. March 8, 2004, a Response submitted by March 8, 2004 will be considered timely. Accordingly, U.S. Serial No. 09/928,178 is pending until March 8, 2004, and this continuation application is timely filed.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 5

**INFORMATION DISCLOSURE STATEMENT**

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56, Applicant would like to direct the Examiner's attention to the add item of U.S. Patent Application No. 09/928,178 on the Information Disclosure Statement (IDS), hereto attached on Form PTO/SB/08A as **Exhibit A** and the Notice of References Cited (PTO-1449) as **Exhibit B**. If the Examiner would like a copy of any of the listed references, Applicant would be pleased to submit said requested references.

In **Exhibit A**, the reference listed as follow:

1. U.S. Patent Application No. 09/928,178, filed on August 9, 2001

In **Exhibit B**, the references listed as follows:

1. Bakhutashvili A, Chikovani T, Bakhutashvili V, Imedidze E. Immunopharmacology of preparation Plaferon-LB. Intern J Immunorehab 1994; 1 (S): 44. (Abstract)
2. Bakhutashvili A, Cheishvili N, Chikovani T, Bakhutashvili V. Plaferon LB - a new immunodilatory drug. Abstracts XVI European Congress of Allergology and Clinical Immunology, Madrid, Spain, 25-30 June 1995. Europ J Allergy Clin Immunol 1995; 50(26): 9. Abstract # OC-009. (Abstract)
3. Bakhutashvili A, Jaguzhinsky L, Bakhutashvili I, Kadagidze Z, et al. Amnion apoptosis modulator. Int J Immunorehab 2001, 3(2): 17-22.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 6

4. Bakhutashvili V, Bakhutashvili A, Chikovani T, Cheishvili N. Immunomodulatory activity of Plaferon-LB. Georg Symp Project Development and Conversion; Collection of Reports 1995; 189-191.
5. Bakhutashvili V, Chikovani T, Rukhadze R. The perspectives of a new immunomodulator Plaferon LB in endocrinologic practice. Proceedings of Tbilisi State Medical University 1996; 32: 21-23.
6. Bakhutashvili V, Malashkhia V, Mikeladze D, Chikhladze M, Malashkhia Y, Bakhutashvili A. Effect of Plaferon-LB during treatment of medicamentously resistant form of epilepsy. Int. J Immunorehab 1996; 3: 28-37.
7. Bakhutashvili V, Javakhishvili N, Tsagareli Z, Kipshidze N. Cardioprotective effects of Plaferon LB in a canine model. The J Heart Failure 1997 May; 4(1): 38. Abstract #151. (Abstract)
8. Bakhutashvili V, Gagua M, Garishvili T, Gelashvili L, Kharebava G, Kvaratskhelia E, Menteshashvili A. Human placenta antioxidant compounds of peptide nature. 11th International Symposium on Atherosclerosis, Paris 1997 October 5-9, Int J Res Invest on Atherosclerosis and Related Diseases October 1997; 134(1-2): 199. Poster # 3.P.4. (Abstract)
9. Bakhutashvili V, Chikovani T, Bakhutashvili I, Cheishvili N, Kukuladze N, Bakhutashvili A. Some pharmacological characteristics of Immunomodulator Plaferon-LB. 10th International Congress of Immunology in New Delhi, 1998 Nov 1-6; The Immunologist 1998 Suppl 1: 586. (Abstract)

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 7

10. Bakhutashvili V, Shakarishvili R, Geladze T, Tatishvili N, Bakhutashvili A, Cheishvili N, Chikovani T, Sobera LA. "Plaferon," Drugs of the Future 1999; 24(9): 974-977.
11. Bakhutashvili V, Telia D, Katsarava V. Use of Plaferon-LB and cromoglycate in patients with symptomatic asthma. Int J Immunorehab 1999; 11: 214-215.
12. Bakhutashvili V, Pagava K, Telia A, Jorjoladze N, Kokaia L, Alavidze M, Kvachadze L. Bronchotropic effect of Plaferon-LB. Int J Immunorehabilitation 1999; 5: 51-53.
13. Bakhutashvili V, Chikovani T, Bakhutashvili A, Dolidze T, Nanava N, Kvitaishvili G. Dinamics of some immunological indices in case of Plaferon-LB therapy. Europ. J. Allergy and Clin Immun 1999; 54(52 S): 77. Abstract # P37. (Abstract)
14. Bakhutashvili V, Chikovani T, Bochorishvili T, Metreveli D, Pavliashvili D. Results of treatment of acute B hepatitis by Plaferon LB. Bulletin of Georgian Academy of Science, Biology Series 1999 25 (1-3):21-23.
15. Bakhutashvili V, Bakradze I, Aladashvili A. Impact of perioperational immunotherapy upon nonspecific resistance and specific immune status in patients with bowel cancer and upon frequency and spectrum of complications in nearest postoperative period. Int J Immunorehab 2000;2 (2): 4. Abstract # 3. (Abstract)
16. Beridze M. Effect of Plaferon-LB on several clinical and neuroimmunological indices. Georgian Medical News 1998; 6(39): 27-30.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 8

17. Beridze M, Malashkhia V, Bakhutashvili V. Neuroprotective action of immunomodulator Plaferon-LB. Int J of Immunorehab 1999; 14: 114. Abstract # 15. (Abstract)
18. Havadagiani G, Chavchanidze D, Kalmahelidze V, Sulhanishvili V, Stepina J, Bakhutashvili V, Managadze L. Protective effect of Plaferon LB preparation on acute ischemic renal injury in experiments. Archivum Urologium Belgrade 1989; 30: 45-51.
19. Chavchanidze D, Sanikidze T, Sul Khanishvili V, Bakhutashvili V, Managadze L. Changes of blood paramagnetic centers under the influence of shock waves on kidneys and membrane-protector effect of Plaferon-LB in experiment. Bulletin of the Georgian Academy of Sciences 1998; 158(2): 332-335.
20. Chavchanidze D, Sanikidze T, Bakhutashvili V, Managadze L. Determination of traumatic influence of shock waves and membrane-protecting effects of Plaferon-LB on the renal parenchyma during extracorporeal lithotripsy in experiment. Proc Georgian Acad Sci; Biol Ser 1998; 24(1-6): 53-59.
21. Cheishvili N, Kukuladze N, Bakhutashvili A, Bakhutashvili V. Effect of Plaferon-LB on proliferative activity of human periferal blood mononuclear cells and murine splenocytes. Reports of Georgian Academy of Science 1994; 150 (1): 142-143.
22. Chikovani T, Cheishvili N, Bakhutashvili A, Bakhutashvili V. The influence of Plaferon LB on synthesis of interleukins. Int J Immunorehab 1996; 3: 96. (Abstract)
23. Chikovani T, Cheishvili N, Pirtskalava T, Pantsulaia I, Bakhutashvili V. Plaferon LB as a blocker of neurotoxic

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 9

effect of glutamate. Int. J Immunorehab 1997; 5: 46.  
(Abstract)

24. Chikovani T, Cheishvili N, Pantsulaia I, Bakhutashvili V. Immunopotential activity of Plaferon LB fractions. Int J Immunorehab 1998; (9): 5. (Abstract)
25. Chikovani T, Pavliashvili D, Bakhutashvili V. Different ways of therapy by Plaferon LB in patients with acute B viral hepatitis. Abstracts of International Falk Workshop, New Aspects in Hepatology and Gastroenterology; May 29-30, 1998; Tbilisi, Georgia. Abstract # 52. (Abstract)
26. Chikovani T, Cheishvili N, Pantsulaia I, Bakhutashvili V, Bakhutashvili A. Immunologic study of human placental factor. Eur J Allergy Clin Immun; 1999; 54 (52 S): 89. Abstract # P81. (Abstract)
27. Chikovani T, Rukhadze R, Bakhutashvili V, Sanikidze T, Pantsulaia I. Antioxidant action of immunomodulatory drug Plaferon LB in experimental thyroid pathology. Int J Immunorehab 1999; 12(S): 14-18.
28. Dolidze Z, Gelovani M, Bakhutashvili V, Chikovani T. Plaferon antirecidive action on the children with idiopathic nephrotic syndrome. Bull Acad Sci Geo 1992; 145 (1): 209-11.
29. Gagua M, Russia L, Kupatadze R, Simonidze M, Bakhutashvili V. Investigation of polipeptide contents of Plaferon LB. Bulletin of Acad of Sci of Georgia 1996; 3(153): 450-452.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 10

30. Gagua M, Dzidziguri D, Bakhutashvili V. Influence of Plaferon LB on the transcriptional activity of regenerating liver and kidney cells. International-European A.I.R.R. Conference; Tbilisi, 1999 October 4-9; Collection of reports: 11. (Abstract)
31. Gagua M, Dzidziguri D, Mikadze E, Rukhadze M, Bakhutashvili I, Bakhutashvili V. Effect of Plaferon LB on morpho-functional activity of hepatocytes under conditions of hormonal disbalance in white rats. Bulletin of Georgian Acad of Sci 1999; 160 (3): 574-576.
32. Gurgenedze G, Chogovadze M, Bakhutashvili V. Plaferon-induced *in vitro* inhibition of mitogen-activated T-lymphocyte proliferation in steroid-resistant asthmatic patients. Trans-Caucasian J Immunology 1999; 1 (2): 12-19.
33. Johnson DW, Kipshidze N, Javahishvili N, Zagareli Z, Bakhutashvili V. Cardioprotective effects of Plaferon-LB in canine model. First International Congress on Heart Disease-New Trends in Research, Diagnosis and Treatment; Washington DC, USA; 1999 May 16-19; Book of Abstracts: 46. Abstract # 30. (Abstract)
34. Macharadze D, Bakhutashvili V, Fedotova E. Plaferon-LB in immuno-rehabilitation of children with bronchial asthma. Int J Immunorehab 1998; 8: 67. Abstract # 249. (Abstract)
35. Maisuradze E, Garishvili T, Bakhutashvili V. Inhibition of Bee Venom Phospholipase A2 activity by Plaferon LB. Bulletin of the Georgian Academy of Sciences 1998; 157, (2): 317-319.



Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 11

36. Beridze M, Malashkhia N, Bakhutashvili V. Immunomodulator Plaferon Lb in the treatment of acute ischemic stroke. Int J Immunorehab 1999; 12: 161-165.
37. Metreveli D, Bakhutashvili V, Bochorishvili T, Jamutashvili M, Gingolava M. Influence of Plaferon-LB on clinical course of Hepatitis and Laboratory Data in Children. International Falk Workshop - New Aspects in Hepatology and Gastroenterology; May 29-30, 1998; Tbilisi, Georgia. Abstract # 195. (Abstract)
38. Metreveli D, Bakhutashvili A, Chikovani T, Pavliashvili D, Bakhutashvili V. Long term results of treatment of B hepatitis with Plaferon LB. Int J Immunorehab 1999; 12: 43. Abstract # 169. (Abstract)
39. Mikeladze D, Djanashia N, Djanashvili C, Bakhutashvili V. Influence of Plaferon upon main excitatory and inhibitory neurotransmitters of brain. Tbilisi 1995; 332-337.
40. Nadareishvili Z, Malashkhia Y, Bakhutashvili V. Plaferon in the treatment of herpes zoster ganglioneuritis in intravenous drug users. Int Conf AIDS, Berlin 1993, June 6-11; 9 (1): 344. Abstract # PO-B08-1254. (Abstract)
41. Pantsulaia I, Chikovani T, Ruhadze R, Sanikidze T, Bakhutashvili V. Influence Plaferon-LB on changes in organs of immune system in case of experimental acute hyperthyroidism. Proceedings of the 4th Republic Scientific Practical Conference, Kutaisi, 1998 May 31; Collection of reports: 24. (Abstract)
42. Pantsulaia I, Chikovani T, Cheishvili N, Garishvili T, Kharebava G, Bakhutashvili V, Zhgenti M. Alteration of

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 12

lymphocytes' proliferative activity *in vitro* under the influence of plaferon LB fractions. Proc Georgian Acad Sci, Biology Series 1999; 25 (1-6): 75-77.

43. Pantsulaia I, Cheishvili N, Kukuladze N, Jgenti M, Chikovani T. Influence of PlaferonLB on proliferative activity of splenocytes in experimental hyper- and hypothyroidism. Int J Immunorehab 2000; 2 (2): 49. Abstract # 157. (Abstract)
44. Pantsulaia I, Pkhakadze E, Cheishvili N, Chikovani T, Jgenti M. Influence of Plaferon LB on the course of moderate periodontitis. Int J Immunorehabilitation 2000; 2 (2): 89. Abstract # 294. (Abstract)
45. Pavliashvili D, Chikovani T, Metreveli D, Sanikidze T, Bakhutashvili V. The effect of sublingual administration of Plaferon LB on metabolic disorders during viral hepatitis B. Georgian Med News 1999; 9 (54): 65-67.
46. Rukhadze R, Sanikidze T, Bakhutashvili V, Chikovani T, Pantsulaia I, Jgenti M. Influence of plaferon LB on metabolic disorders in liver during experimental hyperthyroidism. Proc Georgian Acad Sci, Biol Ser 1998; 24 (1-6): 333-337.
47. Rukhadze R, Sanikidze T, Bakhutashvili V, Chikovani T, Nikoleishvili L, Pantsulaia I, Jgenti M. An interim report on the effect of Plaferon LB on metabolic changes in myocardium during experimental hyperthyroidism. Proc Georgian Acad Sci, Biol Ser 1998; 24 (1-6): 339-343.
48. Rukhadze R, Sanikidze T, Cigovani T, Bakhutashvili V. Influence of Plaferon LB on some indices of liver

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 13

mitochondria during experimental hyperthyroidism.  
Georgian Medical News 1999; 2: 7-9.

49. Rukhadze R, Chikovani T, Bakhutashvili V, Sanikidze T, Metreveli D, Pantsulaia I, Balarjishvili M. Influence of Plaferon LB on the metabolism of nitric oxide (NO) in case of Thyrotoxicosis. Bulletin of Georgian Academy of Science 1999; 160 (3): 580-582.
50. Rukhadze R, Chikovani T, Pantsulaia I, Bakhutashvili V. The influence of Plaferon-LB on some splenic morphometric indices during experimental hyper- and hypothyroidism. Int J Immunorehab 1999; 14: 117. Abstract # 76. (Abstract)
51. Rukhadze R, Chikovani T, Bakhutashvili V, Sanikidze T, Metreveli D, Pantsulaia I, Balarjishvili M. Influence of Plaferon LB on the metabolism of nitric oxide (NO) in case of hypothyroidism. Bulletin of Georgian Academy of Science; 2000, 161 (1): 156-158.
52. Ryazantseva S, Vysotskaja I, Ermilova V, Bakhutashvili V. Immunomorphological changes in breast cancer as a result of preoperative administration of immunomodulator Plaferon. Herald of Oncology. National Center, Russian Academy of Science; Clinical Investigations 1999; 4: 37.
53. Shakarishvili R, Sanikidze T, Mitagvaria N, Beridze M, Mikeladze D, Bakhutashvili V. The role of oxygen and nitrogen reactive species in pathogenesis of ischemic stroke. Report on Scientific Session of NATO, Tbilisi, Georgia, October 2001. In press.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 14

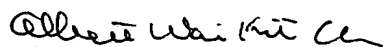
54. Tatishvili N, Bakhutashvili V, Simonia G. Local use of Plaferon LB in rheumathology. Int J Immunorehab 1999; 12: 81. Abstract # 303. (Abstract)
55. Telia À, Bakhutashvili V, Jorjoladze N, Kvachadze L. Use of Plaferon LB in children with bronchial asthma. Int J Immunorehab 1997; 7: 139. (Abstract)
56. Telia À, Bakhutashvili V, Kokaia L, Jorjoladze N, Kvachadze L, Alavidze M. Preventive effect of Plaferon LB on hystamine-induced bronchoconstriction obstruction in guinea pig. Int J Immunorehab 1998; 9: 28. (Abstract)
57. Telia À, Bakhutashvili V, Kokaia L, Alavidze M, Pagava K, Jorjoladze N, Kvachadze L. Plaferon LB as an alternative preparation for treatment of bronchial asthma in children. Int J Immunorehab 1998; 10: 165-167.
58. Telia À, Katsarava V, Bakhutashvili V. Impact of Plaferon LB on bronchial and alveolar cell count and ventilatory function in patients with asthma. Int J Immunorehab 1999; 12 (S): 24.
59. Telia À, Katsarava V Bakhutashvili V, Influence of Plaferon LB on Proportion of Bal cells and Ventilatory Function in Patients with Asthma. Int J Immunorehab 1999; 12: 164-165.

Applicant : Vladimir BAKHUTASHVILI  
U.S. Serial No.: Not Yet Known  
Filing Date : Herewith  
Page : 15

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Preliminary Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

  
Albert Wai-Kit Chan  
Registration No. 36,479  
Attorney for Applicant  
Law Offices of  
Albert Wai-Kit Chan, LLC  
World Plaza, Suite 604  
141-07 20<sup>th</sup> Avenue  
Whitestone, New York 11357  
Tel: (718) 357-8836  
Fax: (718) 357-8615  
E-mail: kitchanlaw@aol.com